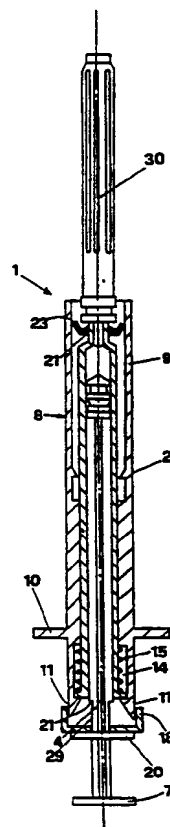




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/EP92/01455 (22) International Filing Date: 29 June 1992 (29.06.92) (30) Priority data: VI91A000107 2 July 1991 (02.07.91) IT (71) Applicants (for all designated States except US): IVALDA SPA [IT/IT]; Via Piovene, 67, I-36010 Chiuppano (IT). PENTAFERTE SRL [IT/IT]; Zona Industriale, I-64012 Campli (IT). (71)(72) Applicant and Inventor (for CA US only): ROMAGNOLI, Paolo [IT/IT]; Viale Adriatico, 45, I-44020 Masi Torello (IT). (74) Agent: BONINI, Ercole; Studio Ing. E. Bonini SAS, 8 Corso Fogazzaro, I-36100 Vicenza (IT).		(81) Designated States: AU, BR, CA, JP, KR, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE). Published <i>With international search report.</i>
(54) Title: SINGLE-SHOT DISPOSABLE SYRINGE (57) Abstract <p>The invention discloses a single-shot disposable syringe for pharmaceutical use which presents in combination: a cylindrical sleeve (8) external to the syringe cylinder (2), equipped with a flange (10) on which the fingers of the hand holding the syringe can rest; a spring (15) placed between the sleeve and the cylinder (2) of said syringe; at least one pair of elastic hooks (11) which are attached to the cylindrical sleeve and which hold the syringe cylinder as long as the plunger (3) of the syringe is not at the end of its stroke; and an intermediate flange (20) on the plunger rod. When the plunger (3) is pushed to the end of the cylinder (2), in order to expell all the liquid contained in the syringe, the intermediate flange (20) on the plunger rod interacts with the elastic hooks (11) disengaging the syringe cylinder from the sleeve. Then under the spring force the syringe cylinder moves relative to the sleeve, so that the needle becomes protected by the sleeve (8).</p>		



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1 SINGLE-SHOT DISPOSABLE SYRINGE

2 The invention discloses a single-shot, disposable syringe
3 for pharmaceutical use of the type with a needle which is
4 protected after the injection has been given.

5 As it is well known, the main purpose proposed by the
6 manufacture of a single-shot, disposable syringe having its
7 needle protected after the injection has been given, is
8 that of preventing as much as possible all the contamina-
9 tion and infection accidents which may arise from the
10 voluntary or the accidental contact with a needle of an
11 already used syringe.

12 Particularly the spreading of highly contagious diseases,
13 such as AIDS or viral hepatitis leads the health authori-
14 ties to promote the use of single-shot, disposable syr-
15 inges, yielding certain hygenical unrenounceable guaran-
16 tees, such that they can prevent infection accidents after
17 they have been used.

18 The single-shot, disposable syringes having a needle which
19 is protected after they have been used, are made essential-
20 ly of a plastic syringe complete with a device protecting
21 the needle which is activated after the injection has been
22 given and which in fact prevents both the use of the same
23 syringe for subsequent injections, and the contact, however
24 accidental, of the already used needle.

25 The Italian patent application 22810/A/88 describes a
26 single-shot disposable syringe, wherein, after the injec-
27 tion has been given and the plunger rod has been released,
28 the needle goes back inside the syringe body because of the
29 action of a spring and, should there be an attempt at re-
30 using it, the tip of the needle is blocked against a small
31 block contained within the protecting element, so that the
32 needle itself no longer finds its way out of the exit
33 opening.

34 The mechanism constituting said invention is made of a
35 large number of components and is, therefore, extremely

1 costly and fairly complicated to manufacture.

2 The purpose of the present invention is to overcome the
3 mentioned inconveniences.

4 The first purpose is that of obtaining a single-shot,
5 disposable syringe preventing anybody from using it again
6 after it has been used once, wherein the needle is protec-
7 ted immediately after the injection has been given.

8 In fact, the purpose proposed by the invention is that of
9 preventing any accidental contamination for the medical
10 operators both during the process of giving injections and
11 during the process of collecting the used syringes and
12 disposing of them. It also has the purpose of preventing
13 accidents of infectious contamination among the population
14 or the sanitations operators whose task it is to collect
15 the used syringes.

16 It is also proposed to prevent contagion among drug addicts
17 issuing from the promiscuous use and from the renewed use
18 of syringes.

19 All the mentioned purposes and others, which will be better
20 described hereinafter, are reached by a single-shot, dispo-
21 sable syringe according to the invention which, in com-
22 pliance with the first claim comprises;

23 - a syringe consisting of a cylinder within which slides a
24 plunger activated by a rod, wherein an injection needle is
25 attached at the end of said syringe having a narrower
26 section;

27 - an injection needle attached to said cylinder;

28 - a cap covering the needle;

29 - a cylindrical sleeve suited to hold in its interior the
30 cylinder of the syringe and to maintain said position
31 through some elastic hooks;

32 - a spring or equivalent elastic means positioned between
33 the sleeve and the cylinder of said syringe,

34 characterized in that it presents in combination:

35 - an outer flange belonging to the sleeve and made so that

1 the fingers of the hand engaging the syringe giving the
2 injection can rest on it;

3 - at least one pair of elastic hooks belonging to the
4 sleeve and suited to hold back the lower rim of the syringe
5 plunger when the syringe plunger has not reached the end of
6 its stroke, the spring positioned between said sleeve and
7 said cylinder being under stress;

8 - an intermediate flange belonging to the plunger rod and
9 positioned close to the rod-pushing flange, said interme-
10 diate flange being suited to co-operate with the terminal
11 parts of said hooks, in that it opens them up, thereby
12 unhooking them and causing the cylinder of the syringe to
13 draw back from the cylindrical sleeve;

14 - blocking means preventing the further reciprocal sliding
15 between the syringe cylinder and the sleeve, after the
16 syringe has drawn back in relation to the sleeve, once the
17 injecting operation has been completed.

18 According to the invention, the single-shot, disposable
19 syringe allows the syringe itself to draw back immediately
20 in relation to the cylindrical sleeve, said sleeve remain-
21 ing firmly in the hand of the operator giving the injec-
22 tion. Thus, the result is that not only does the needle go
23 back into the protected area of the cylindrical sleeve, but
24 also that no shock is caused by the syringe or by its
25 protection to the part of the body interested by the injec-
26 tion.

27 According to a preferred embodiment of the invention, the
28 presence of an elastic washer which is restrained within an
29 annular recess of the cylindrical sleeve when the syringe
30 slides back, prevents the repetition of the forward sli-
31 ding motion of the syringe cylinder and, therefore, of the
32 needle which is attached to it, thereby preventing a rene-
33 wed use of the syringe or, at any rate, preventing the
34 needle from coming out of the protected area inside the
35 sleeve.

1 Further scope of applicability of the present invention
2 will become apparent from the detailed description given
3 hereinafter. However, it should be understood that the
4 detailed description and specific examples, while indica-
5 ting preferred embodiments of the invention, are given by
6 way of illustration only, since various changes and modifi-
7 cations within the spirit and scope of the invention will
8 become apparent to those skilled in the art from this
9 detailed description and from the drawings, wherein;

10 - Fig. 1 shows in a cross-section the syringe of the inven-
11 tion before it is used;

12 - Fig. 2 shows the syringe of the invention during the
13 suction phase with the safety bushing free from the hooks
14 which held it before;

15 - Fig. 3 shows again the syringe during the injection,
16 without the safety bushing;

17 - Fig. 4 shows the syringe during the injecting operation
18 while the plunger is reaching its position of maximum
19 pressure;

20 - Fig. 5 shows the withdrawal of the syringe in relation to
21 the sleeve protecting the needle after the injection;

22 - Fig. 6 shows an exploded view of the components of the
23 single-shot, disposable syringe of the invention.

24 With reference to the mentioned figures, it can be observed
25 that the syringe according to the invention, indicated as a
26 whole with 1, presents a cylinder 2, within which slides
27 plunger 3, activated by rod 4. The end of cylinder 2 having
28 a narrower and tapered section, as indicated in 5, or
29 better said, the section of a truncated cone, is suited to
30 receive a needle 6. The rod 4 of plunger 3 ends with a
31 pushing flange 7, which is the flange on which pressure is
32 exerted in order to give the injection.

33 The components which have been described so far are nothing
34 more than the components which usually make up a single-
35 shot syringe: in fact the following components have been

1 described: the cylinder, the plunger with the rod and the
2 needle, all of them being the components which are used for
3 the present invention, using those already on the market,
4 with the exception of some minor modifications.

5 The novelty of the syringe of the invention consists, in
6 fact, of the presence of the cylindrical sleeve 8 and in
7 the way said sleeve inter-acts with the rest of the syrin-
8 ge.

9 As can be observed in the different figures of drawing and
10 especially in Fig. 5, the cylindrical sleeve 8 comprises a
11 cylindrical part 9 ending with a lower flange 10, which is
12 meant as a support for the fingers of the hand holding the
13 syringe while giving the injection.

14 The cylindrical sleeve 8 ends with a pair of hooks 11, each
15 consisting of a tooth 12 presenting a slanted surface 13
16 extending outward toward the end of the sleeve itself.

17 In the interior, comprised between the tooth 12 and the
18 area near the flange 10, there is a cylindrical space 14.
19 Within this space there is a cylindrical spring 15, one end
20 of which rests against the bead 16 belonging to the sleeve
21 8, while its other end rests against the rim 17 which
22 constitutes the end of cylinder 2 into which plunger 4 is
23 inserted.

24 In the resting position, i.e. when the syringe is new and
25 has not been used yet, as can be observed in Fig. 1, spring
26 15 is compressed within the annular space 14 and cylinder 2
27 is kept in its position by the hooks 11 which prevent it
28 from being pushed in the direction opposite the needle; the
29 needle is protected by a cap 30 whose shape and function
30 belong to the known technique.

31 In order to prevent accidental openings due to the sprea-
32 ding apart of the hooks 11, the new syringe is provided
33 with a safety bushing 18, having an essentially cylindri-
34 cal, innerly hollow shape and it presents a bottom with an
35 opening 19, as can be seen in Fig. 6, extending also along

1 the cylindrical wall, the width of said opening being equal
2 to the diameter of rod 4 in the area of rod 4 itself, which
3 has a narrower section than the rest and extends for a
4 certain stretch from the intermediate flange 20 over an
5 area immediately adjacent to the same and extending toward
6 plunger 3.

7 It is easy to understand that, when in its resting posi-
8 tion, as can be observed in Fig. 1, the safety bushing 18
9 holds in its interior the hooks 11 and prevents them from
10 opening up and, therefore, from freeing the syringe cylin-
11 der. As soon as the rod 4 of plunger 3 begins to move and
12 to suck in the liquid, as can be seen in Fig. 2, the bus-
13 hing 18 frees itself from the hooks 11, since it is trailed
14 along by the beat 21, because of the difference in the
15 diameter of rod 4 in the indented area 29.

16 Once the disengagement between the safety bushing 18 and
17 the hooks 11 has occurred, the bushing itself can be elimi-
18 nated, or, more frequently, it falls off because of the
19 force of gravity, since its center of gravity is asymmetri-
20 cal in relation to the geometrical axis of the same, so
21 that it is possible for the bushing to fall down.

22 Fig. 3 shows the syringe according to the invention while
23 it is sucking in the liquid to be injected and Fig. 4 shows
24 the final stage of the liquid injection, when plunger 3
25 reaches the bottom of the cylinder 2. While in this posi-
26 tion, it can be observed that the intermediate flange 20
27 causes the pair of hooks 15 to spread apart, so that it is
28 possible for cylinder 2 to slide in the direction opposed
29 to that of the needle, since it is pushed by the compressed
30 spring 15, as can be seen in Fig. 5.

31 The condition is thus created, that when the plunger rea-
32 ches the bottom of the cylinder and the injecting operation
33 has, therefore, been completed, the syringe cylinder disen-
34 gages itself and the cylinder slides back in the direction
35 opposed to that of the needle, thereby allowing the needle

1 6 to enter into the protective sleeve 8. In the area of the
2 sleeve presenting a narrower section 5, before the needle
3 6, there is an elastic washer 21 which, as can be better
4 observed in Fig 6, has the shape of a truncated cone and
5 presents a set of elastic cogs 23, so that, when the needle
6 6 slides backwards because it is trailed along by cylinder
7 2, said washer positions itself within an annular indenta-
8 tion 22 which is present in the inner wall of sleeve 8. It
9 is obvious that any action aimed at pushing again both the
10 rod and the syringe cylinder with the purpose of pushing
11 the needle 6 out of the protecting sleeve 8 is prevented by
12 the presence of the washer 21, whose cogs 23 contrast
13 against the wall 24 formed by the indentation 22. Thus it
14 is impossible to use the syringe more than once for subse-
15 quent injections and it is guaranteed that the needle can
16 never go out of the protecting sleeve 8.

17 Thus it has been seen how the single-shot, disposable
18 syringe according to the invention has reached all the
19 proposed purposes. In fact, it has been seen how the needle
20 withdraws immediately when, after reaching the end of its
21 stroke, the plunger ends its pushing action. It has also
22 been observed how any subsequent attempt at letting the
23 needle out or, at any rate, at re-using the syringe is
24 prevented by the presence of a washer positioned in the
25 indentation belonging to the inner surface of the cylindri-
26 cal protecting sleeve.

27 It is apparent that the invention, such as it has been
28 described, can undergo changes during the manufacturing
29 stage; for instance, it will be possible to change the
30 number or the shape of the hooks holding the syringe cylin-
31 der in position; it will also be possible to change the
32 type of washer or of the elastic means which permits the
33 jamming of the cylinder, should there be an attempt at a
34 subsequent re-utilization. However, all said changes will
35 be considered as belonging to the scope of the invention,

1 such as it is described in the following claims.

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1 CLAIMS

2 1) A single-shot, disposable syringe for pharmaceutical
3 use, comprising:

- 4 - a cylinder (2) within which slides a plunger (3) activa-
5 ted by a rod (4), wherein an injection needle is attached
6 at the end (5) of said syringe having a narrower section;
7 - an injection needle (6) attached to said cylinder;
8 - a cap (30) covering the needle;

9 characterized in that it presents in combination:

10 - a cylindrical sleeve (8) suited to hold in its interior
11 the cylinder of the syringe and to maintain said position
12 through some elastic hooks (11);

13 - an outer flange (8) belonging to the sleeve (8) and made
14 so that the fingers of the hand engaging the syringe giving
15 the injection can rest on it;

16 - a spring (15) or equivalent elastic means positioned
17 between the sleeve (8) and said syringe cylinder (2)

18 - at least one pair of elastic hooks (11) belonging to the
19 sleeve (8) and suited to hold back the lower rim (17) of
20 the syringe cylinder when the syringe plunger (3) has not
21 reached the end of its stroke, the spring (15) positioned
22 between said sleeve and said cylinder being under stress;

23 - an intermediate flange (20) belonging to the rod pushing
24 the plunger and positioned close to the rod-pushing flange
25 (7), said intermediate flange (20) being suited to co-
26 operate with the terminal parts of said hooks, in that it
27 opens them up, thereby unhooking them and causing the
28 syringe cylinder (2) to withdraw from the cylindrical
29 sleeve, because of the elastic return of the spring;

30 - blocking means preventing the further reciprocal sliding
31 between the sleeve (8) and the syringe cylinder (2), after
32 the syringe has drawn back in relation to the sleeve, as
33 soon as the injecting operation has been completed.

34 2) A syringe according to claim 1, characterized in that
35 the blocking means preventing any further sliding between

1 the sleeve (8) and the syringe cylinder (2) after the first
2 use is an elastic washer (21) arranged around the narrower
3 section (5) of the syringe cylinder (2), between said
4 cylinder and the needle (6), said elastic washer (21) being
5 suited to be restrained within an annular indentation (22)
6 belonging to the inner surface of the sleeve, when the
7 syringe cylinder slides back at the end of the injecting
8 operation.

9 3) A syringe according to claim 1, characterized in that it
10 presents a safety bushing (18) having an essentially cylin-
11 drical shape, being innerly hollow and with a bottom pre-
12 senting an opening (19) extending also along the cylindri-
13 cal wall, its width being such that it is positioned along
14 the area (29) of the plunger-pushing rod having a narrower
15 section, the inner cylindrical surface of said bushing
16 restraining the outer surface of said at least one pair of
17 hooks (11) when the syringe is not used, said bushing (18)
18 disengaging itself from the restriction of said hooks and
19 coming off the syringe when the plunger rod of the syringe
20 moves for the suction action.

21 4) A syringe according to claim 1, characterized in that
22 the safety bushing (18) has a center of gravity which is
23 considerably off center in relation to the geometrical
24 axis of said bushing, so as to fall off the syringe because
25 of the force of gravity when it is free from the hooks of
26 the sleeve (8).

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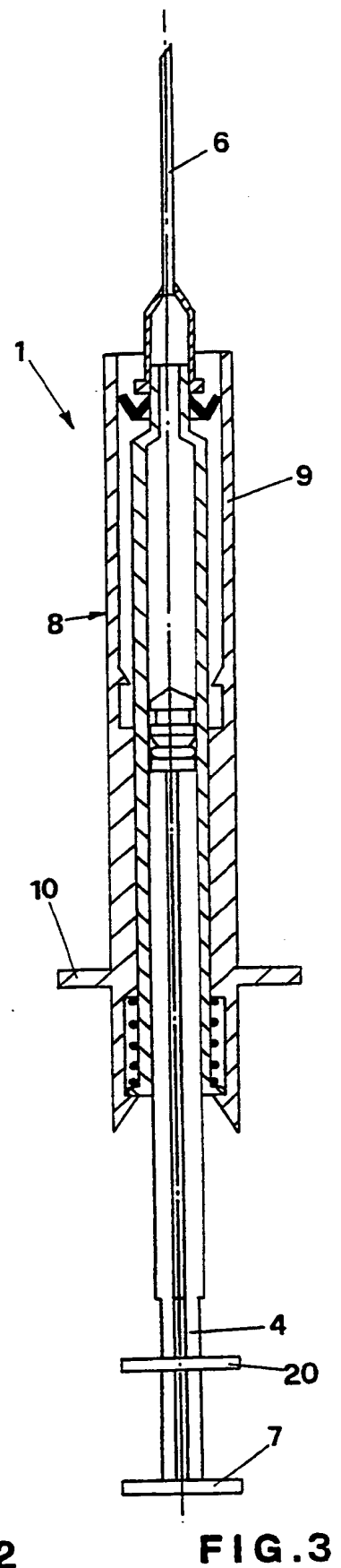
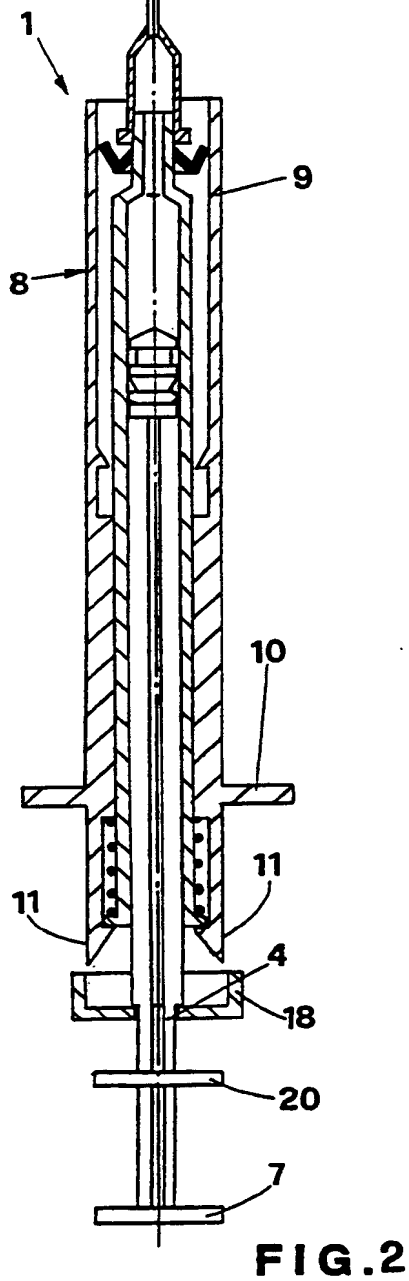
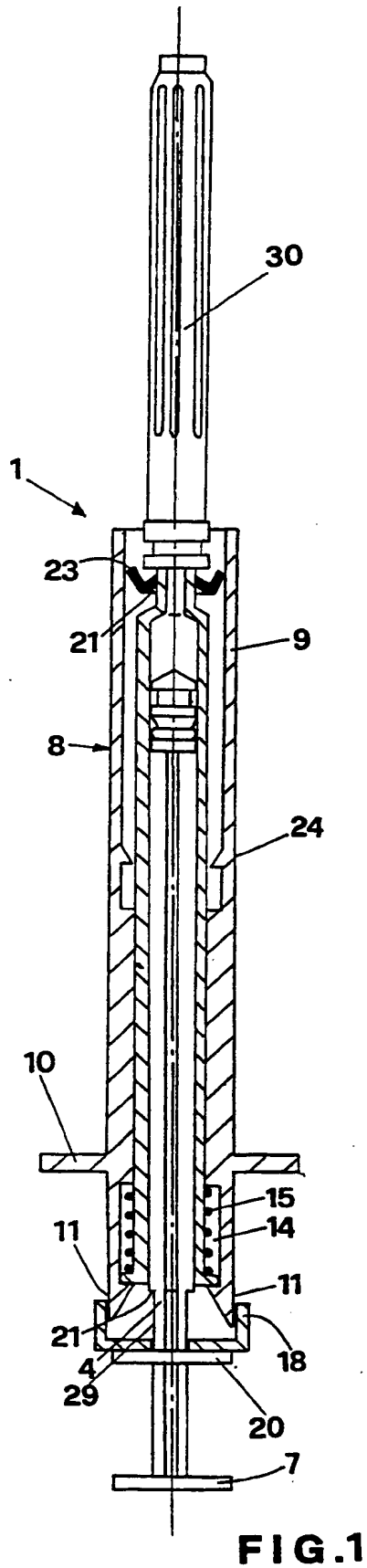
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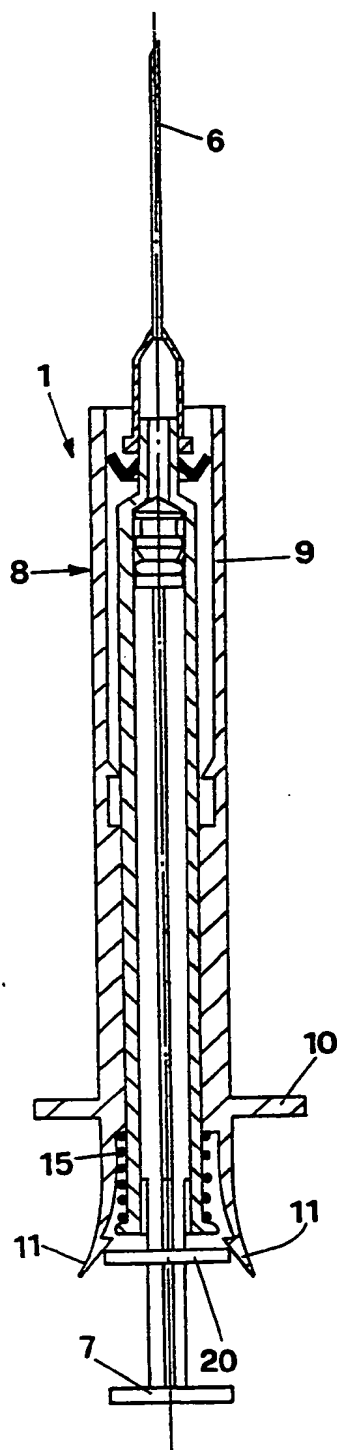


FIG. 4

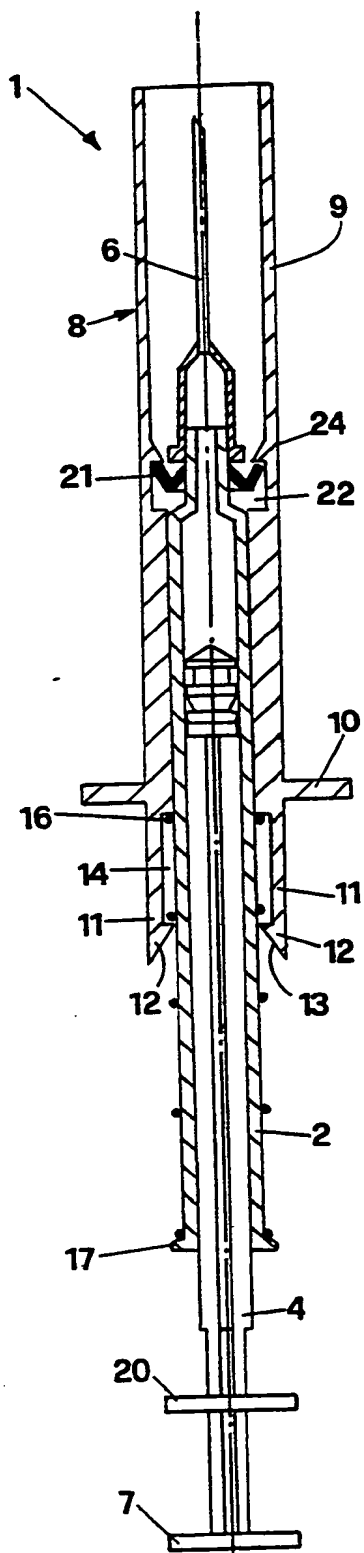


FIG. 5

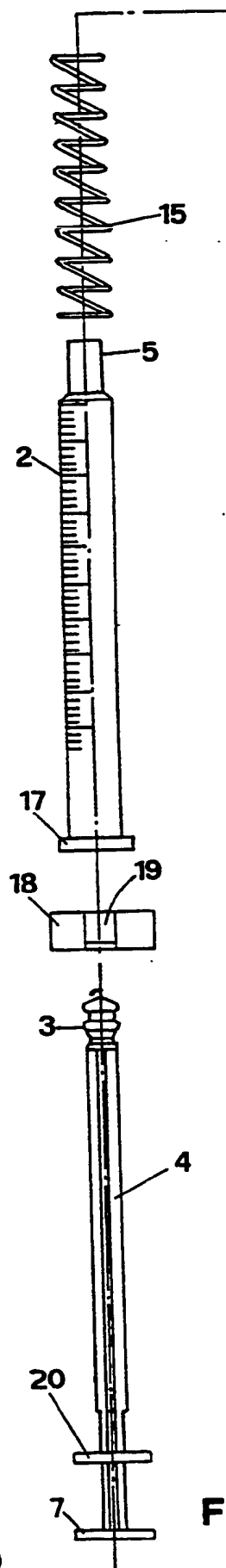
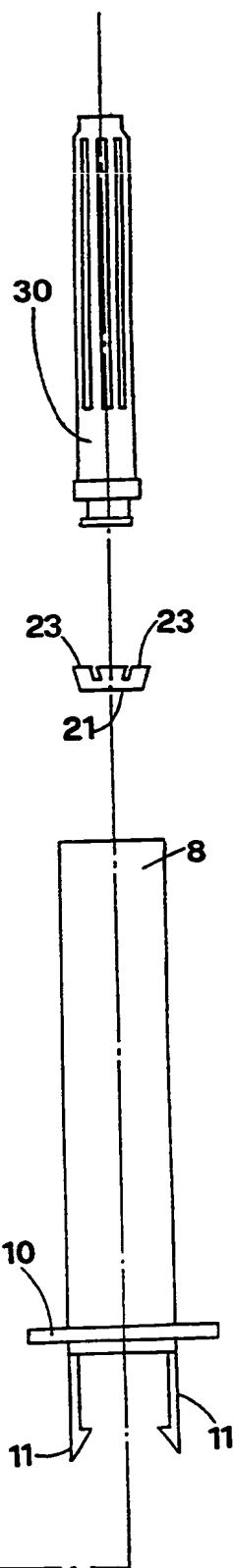


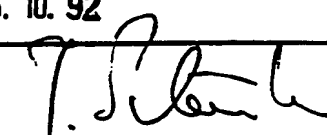
FIG. 6



INTERNATIONAL SEARCH REPORT

International Application N

PCT/EP 92/01455

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M5/32		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	FR,A,2 650 187 (GUERINEAU ET POIRIER) 1 February 1991 see page 3, line 2 - page 5, line 3 see page 6, line 13 - line 35 see figures 1-3,9,10 ---	1,2
X	EP,A,0 307 367 (AR.MA.S.R.L.) 15 March 1989 see column 4, line 39 - line 52 see column 5, line 63 - column 7, line 27 see figures 7-11 ---	1
A	DE,A,3 842 107 (BADER) 21 June 1990 see column 2, line 65 - column 3, line 25 see figures 3,4 ---	2
-/-		
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
10 SEPTEMBER 1992	06.10.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	SCHOENLEBEN J. 	

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category ^a	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X,P	EP,A,0 467 173 (RIGHI) 22 January 1992 see column 4, line 46 - column 6, line 44 see column 9, line 21 - line 58 see figures 1-4,9 ---	1-3

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. EP 9201455
SA 62560**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A-2650187	01-02-91	FR-A- 2648716 WO-A- 9113643 EP-A- 0405039	28-12-90 19-09-91 02-01-91
EP-A-0307367	15-03-89	DE-A- 3872122 JP-A- 1043268 US-A- 4850968	23-07-92 15-02-89 25-07-89
DE-A-3842107	21-06-90	None	
EP-A-0467173	22-01-92	CA-A- 2047263	20-01-92

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